UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of NATURAL ORGANICS, INC., a corporation, and GERALD A. KESSLER, individually and as an officer of the corporation.	)	DOCKET NO. 9294

ORDER GRANTING MOTION BY THE U.S. FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA

Respondents, on February 26, 2001, served two subpoenas. One requested Mr. David Read of the Food and Drug Administration ("FDA") to appear for a deposition. The second subpoena directed FDA's Center for Drug Evaluation and Research ("CDER") to produce responsive documents. On March 9, 2001, the FDA filed the instant motion to quash the subpoena *duces tecum*. The FDA did not move to quash the subpoena seeking the deposition testimony of Mr. Read. Respondents filed their opposition on March 19, 2001. For the reasons set forth below, the FDA's motion is GRANTED, as set forth herein.

On January 8, 2001, Complaint Counsel notified Respondents that it contemplates calling David T. Read, Supervisory Regulatory Counsel with CDER, as a fact witness in this proceeding. Complaint Counsel has represented that Read will testify about FDA's regulation of deanol in the FDA's Drug Efficacy Study Implementation ("DESI") proceeding. The FDA has represented that the CDER's only participation in this case is the proposed testimony of CDER employee Read as a fact witness to explain the FDA's role in the regulation of deanol.

Complaint Counsel has represented that Read will not testify on the following topics: whether the FDA has made any conclusions about the efficacy of Respondents' product; whether the FDA's actions on a similar product establish that Respondents lack a reasonable basis for their claims under the FTC Act; whether the FDA has determined that deanol is not effective;

or whether any product that contains deanol and is intended to treat, mitigate, or otherwise affect ADD/ADHD or its symptoms must have an approved new drug application before it can be marketed lawfully. The FDA has also represented that Read will not testify as to the efficacy of deanol or Pedi-Active A.D.D. Based on these representations and the FDA's refusal to produce all documents responsive to Respondents' subpoena, the testimony Complaint Counsel seeks to elicit from Read or any other employee of the FDA at trial will be confined.

The FDA has represented that the only information pertinent to Read's testimony would be in CDER's DESI file. The FDA has further stated it does not consider the production of documents related to its regulation of deanol in its DESI proceeding to be unreasonable or irrelevant. On March 15, 2001, the FDA did produce to Respondents the contents of the DESI file for Deaner tablets. Because Read is intended to testify to a narrowly limited topic and because the FDA has already produced documents relevant to that topic, the FDA's motion to quash is GRANTED.

Because Complaint Counsel intends to present Read as a fact witness, Respondents must have the opportunity to depose Read. The FDA has not filed a motion to quash the subpoena *ad testificandum* served on Read. Accordingly, Respondents are entitled to depose Read at a time and location mutually agreeable. In addition, because Read is Complaint Counsel's witness, to the extent that Complaint Counsel has not done so already, Complaint Counsel is required to furnish Respondents, in sufficient time in advance of the Read deposition, all non-privileged documents that Complaint Counsel has received from the FDA that are responsive to the Respondents' subpoena or are relevant to the issues in this proceeding.

James P. Timony
Administrative Law Judge

Dated: March 26, 2001